REMARKS

Applicant respectfully submits that no new matter has been added to the specification by this amendment. None of the amendments are to be construed as dedicating any unclaimed subject matter to the public, and Applicant reserves the right to claim any subject matter supported by the specification in this or future related applications. Submitted below is a separate page titled "Version with Marking to Show Changes Made to the Claims," showing a marked-up copy of prior pending claims. Applicant further submits that the pending claims 1-6, 8-14, 17-23, 25-32, 34-36, 75-83, 85-88, 91-97, 99-106, 108-118, 120-126, 129-135, 137-144, and 146-361 are patentable, and that they be passed to allowance.

Respectfully submitted,

THE CURATORS OF THE
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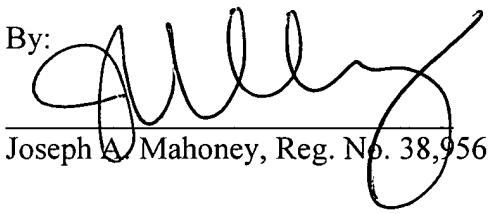
By: 

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Version with Marking to Show Changes Made to the Claims

1. (Amended) A method of treating a gastric acid related disorder in [increasing absorption of a proton pump inhibiting agent into blood serum of] a subject, comprising:

providing a solid pharmaceutical composition for oral administration to the subject, the composition comprising a therapeutically effective amount of at least one acid labile, substituted benzimidazole H^+,K^+-ATPase [the] proton pump inhibitor [inhibiting agent] and an amount of at least one [a] buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid so as to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 μg/ml at any time within about 30 minutes after administration of the composition; and

orally administering the pharmaceutical composition to the subject [subject's stomach whereby the composition contacts gastric fluid of the stomach and increases the absorption of the proton pump inhibiting agent into the blood serum in an amount greater than the absorption of the proton pump inhibiting agent in the absence of the buffering agent;

wherein the buffering agent is in an amount sufficient to increase gastric fluid pH of the stomach to a pH that inhibits acid degradation of the proton pump inhibiting agent in the gastric fluid so as to provide a measurable serum concentration upon pharmacokinetic testing].

2. (Amended) The method of claim 1, wherein the composition is administered in an amount to achieve an initial [a measurable] serum concentration of the proton pump inhibitor [inhibiting agent] greater than about 0.15 μg/ml at any time within about 30 [15] minutes after administration [ingestion] of the composition.

3. (Amended) The method of claim 1, wherein the composition is administered in an amount to achieve an initial [a measurable] serum concentration of the proton pump inhibitor [inhibiting agent] greater than about 0.15 μg/ml at any time within [from] about 20 [15] minutes [to about 1 hour] after administration [ingestion] of the composition.

4. (Amended) The method of claim 1, wherein the composition is administered in an amount to maintain [achieve] a measurable serum concentration of the proton pump inhibitor [inhibiting agent] greater than about 0.15 μg/ml from about 10 [15] minutes to about 30 minutes [1.5 hours] after administration [ingestion] of the composition.

5. (Amended) The method of claim 1, wherein the composition is administered in an amount to achieve [a measurable] an initial serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.1 μg/ml within about 15 minutes after [ingestion] administration of the composition.

6. (Amended) The method of claim 1, wherein the composition is administered in an amount to achieve [a measurable] an initial serum concentration of the proton pump [inhibiting agent] inhibitor greater than about [0.1] 0.15 μg/ml [from] at any time within about 15 minutes [to about 1.5 hours] after [ingestion] administration of the composition.

8. (Amended) The method of claim 1, wherein the pharmaceutical composition is in a form selected from the group consisting of a tablet, capsule, powder, suspension tablet, effervescent tablet or capsule, chewable tablet, granules, pellets, and a liquid created by mixing any of the foregoing with an aqueous medium.

9. (Amended) The method of claim 1, wherein at least some of the proton pump [inhibiting agent] inhibitor is [enteric] coated.

10. (Amended) The method of claim 1, wherein the amount of the proton pump [inhibiting agent] inhibitor absorbed into the [blood] serum is therapeutically effective in treating [an] the gastric acid related [gastrointestinal condition] disorder selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, heartburn, esophageal disorder, and acid dyspepsia.

11. (Amended) The method of claim 1, wherein the proton pump [inhibiting agent] inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

12. (Amended) The method of claim 1, wherein the amount of the proton pump [inhibiting agent] inhibitor is about [5] 2 mg to about 300 mg.

13. (Amended) The method of claim 1, wherein the amount of the proton pump [inhibiting agent] inhibitor is about 10 mg to about [100] 120 mg.

14. (Amended) The method of claim 1, wherein the amount of the proton pump [inhibiting agent] inhibitor is about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

20. (Amended) The method of claim 1, wherein the amount of the buffering agent is about [20] 15 mEq to about [40] 55 mEq.

23. (Amended) The method of claim 1, wherein the buffering agent [comprises at least one of] is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, [or] magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, sodium dihydrogen phosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

27. (Amended) The method of claim 25, wherein the sodium bicarbonate is in an amount from about 1000 mg to about [1680] 2000 mg

28. (Amended) The method of claim 25, wherein the sodium bicarbonate is in an amount of at least about [800] 400 mg.

31. (Amended) The method of claim 29, wherein the calcium carbonate is in an amount from about [500] 1000 mg to about [1000] 2000 mg.

32. (Amended) The method of claim 29, wherein the calcium carbonate is in an amount of at least about [800] 400 mg.

34. (Amended) The method of claim 1, wherein the composition further comprises [a] at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, [excipient,] a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing [or a pharmaceutically compatible carrier].

35. (Amended) The method of claim 1, wherein the composition further comprises [a] one or more flavoring agents comprising aspartame, thaumatin, sucrose, dextrose, or a chocolate, a cocoa, a cola, a peppermint, a spearmint, a watermelon, an apple, a caramel, a meat, a root beer, [peppermint, spearmint, or watermelon,] a maple, a cherry, a coffee, a mint, a licorice, a nut, a butter, a butterscotch, a butter pecan, or a peanut butter flavoring, and combinations of any of the foregoing.

75. (Amended) A method of treating [an] a gastric acid related [gastrointestinal] disorder in a subject in need thereof, comprising:

orally administering to the subject a pharmaceutical composition in an oral dosage form for immediate release into an absorption pool having a highly acidic pH, the composition comprising a therapeutically effective amount of at least one acid labile, substituted benzimidazole H^+,K^+-ATPase proton pump [inhibiting agent] inhibitor, and an amount of at least one [a] buffering agent sufficient to increase the pH of the absorption pool of the subject to a pH that prevents acid degradation of at least some of the proton pump inhibitor so as to achieve an

initial serum concentration of the proton pump inhibitor greater than about 0.1 μg/ml at any time within about 30 minutes after administration of the composition.[;]

[wherein the buffering agent is in an amount sufficient to increase the pH of the absorption pool of the subject to a pH that inhibits acid degradation of the proton pump inhibiting agent and to allow absorption of the proton pump inhibiting agent from the absorption pool into blood serum of the subject in an amount greater than the absorption of the proton pump inhibiting agent in the absence of the buffering agent; and]

[wherein the proton pump inhibiting agent is in an amount sufficient to achieve a measurable serum concentration in the blood serum of the subject after oral administration to the subject.]

76. (Amended) The method of claim 75, wherein the composition is administered in an amount to achieve [a measurable serum] an initial serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.15 μg/ml at any time within about [15] 30 minutes after administration of the composition.

77. (Amended) The method of claim 75, wherein the composition is administered in an amount to [achieve a measurable] maintain a serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.15 μg/ml from about [15] 10 minutes to about [1 hour] 30 minutes after administration of the composition.

78. (Amended) The method of claim 75, wherein the composition is administered in an amount to achieve [a measurable] an initial serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.15 μg/ml [from] at any time within about [5] 20 minutes [to about 1.5 hours] after administration of the composition.

79. (Amended) The method of claim 75, wherein the composition is administered in an amount to achieve [a measurable] an initial serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.1 μg/ml at any time within about 15 minutes after administration of the composition.

80. (Amended) The method of claim 75, wherein the composition is administered in an amount to achieve [a measurable] an initial serum concentration of the proton pump [inhibiting agent] inhibitor greater than about [0.1] 0.15 μg/ml [from] within about 15 minutes [to about 1.5 hours] after administration of the composition.

82. (Amended) The method of claim 75, wherein the pharmaceutical composition is in a form selected from the group consisting of a tablet, capsule, powder, suspension tablet, effervescent tablet or capsule, chewable tablet, granules, pellets, and a liquid created by mixing any of the foregoing with an aqueous medium.

83. (Amended) The method of claim 75, wherein the proton pump [inhibiting agent] inhibitor is [enteric] coated.

85. (Amended) The method of claim 75, wherein the proton pump [inhibiting agent] inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

86. (Amended) The method of claim 75, wherein the amount of the proton pump [inhibiting agent] inhibitor is [in an amount of] about [5] 2 mg to about 300 mg.

87. (Amended) The method of claim 75, wherein the amount of the proton pump [inhibiting agent] inhibitor is about 10 mg to about [100] 120 mg.

88. (Amended) The method of claim 75, wherein the amount of the proton pump [inhibiting agent] inhibitor is about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

94. (Amended) The method of claim 75, wherein the amount of the buffering agent is about [20] 15 mEq to about [40] 55 mEq.

97. (Amended) The method of claim 75, wherein the buffering agent [comprises at least one of] is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, sodium dihydrogen phosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate,

trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

101. (Amended) The method of claim 99, wherein the sodium bicarbonate is in an amount from about 1000 mg to about [1680] 2000 mg

102. (Amended) The method of claim 99, wherein the sodium bicarbonate is in an amount of at least about [800] 400 mg.

105. (Amended) The method of claim 103, wherein the calcium carbonate is in an amount from about [500] 1000 mg to about [1000] 2000 mg.

106. (Amended) The method of claim 103, wherein the calcium carbonate is in an amount of at least about [800] 400 mg.

108. (Amended) The method of claim 75, wherein the composition further comprises at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, [excipient, colorant,] a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or [a pharmaceutically compatible carrier] an isotonic agent, and combinations of any of the foregoing.

110. (Amended) The method of claim 75, wherein the disorder is selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, heartburn, esophageal disorder, and acid dyspepsia.

111. (Amended) The method of claim 75, wherein the composition further comprising [a] one or more flavoring agents comprising aspartame, thaumatin, sucrose, dextrose, or a chocolate, a cocoa, a cola, a peppermint, a spearmint, a watermelon, an apple, a caramel, a meat, a root beer, [peppermint, spearmint, or watermelon,] a maple, a cherry, a coffee, a mint, a licorice, a nut, a butter, a butterscotch, a butter pecan, or a peanut butter flavoring, and combinations of any of the foregoing.

113. (Amended) A method of making a pharmaceutical composition for oral administration to a subject, [providing immediate release of a proton pump inhibiting agent and a buffering agent into an absorption pool having a highly acidic pH,] comprising:

admixing a therapeutically effective amount of at least one acid labile, substituted benzimidazole H^+,K^+-ATPase [the] proton pump [inhibiting agent] inhibitor and an amount of at least one [the] buffering agent sufficient to increase the pH of an absorption pool of the subject to a pH that prevents acid degradation of at least some of the proton pump inhibitor so as to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 μg/ml at any time within about 30 minutes after administration of the composition.[;]

[wherein the buffering agent is in an amount sufficient to increase the pH of the absorption pool of the subject to a pH that inhibits acid degradation of the proton pump inhibiting agent and to allow absorption of the proton pump inhibiting agent from the absorption pool into blood serum of the subject in an amount greater than the absorption of the proton pump inhibiting agent in the absence of the buffering agent; and]

[wherein the proton pump inhibiting agent is in an amount sufficient to achieve a measurable serum concentration in the blood serum of the subject after oral administration to the subject.]

114. (Amended) The method of claim 113, wherein [the amount of buffering agent] the composition is administered in an amount to achieve[s] an initial [measurable] serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.15 μg/ml at any time within about [15] 30 minutes after administration of the composition.

115. (Amended) The method of claim 113, wherein the [amount of buffering agent achieves a measurable] composition is administered in an amount to maintain a serum

concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.15 μg/ml from about [15] 10 minutes to about [1 hour] 30 minutes after administration of the composition.

116. (Amended) The method of claim 113, wherein the [amount of buffering agent] composition is administered in an amount to achieve[s] an initial [measurable] serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.15 μg/ml [from] at any time within about [15] 20 minutes [to about 1.5 hours] after administration of the composition.

117. (Amended) The method of claim 113, wherein the [amount of buffering agent] composition is administered in an amount to achieve[s] an initial [measurable] serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.1 μg/ml at any time within about 15 minutes after administration of the composition.

118. (Amended) The method of claim 113, wherein the [amount of buffering agent] composition is administered in an amount to achieve[s] an initial [measurable] serum concentration of the proton pump [inhibiting agent] inhibitor greater than about 0.1 μg/ml [from] at any time within about 15 minutes [to about 1.5 hours] after administration of the composition.

120. (Amended) The method of claim 113, wherein the pharmaceutical composition is in a form selected from the group consisting of a tablet, capsule, powder, suspension tablet, effervescent tablet or capsule, chewable tablet granules, pellets, and a liquid created by mixing any of the foregoing with an aqueous medium.

121. (Amended) The method of claim 113, wherein the proton pump [inhibiting agent] inhibitor is [enteric] coated.

122. (Amended) The method of claim 113, wherein the proton pump [inhibiting agent] inhibitor is acid sensitive.

123. (Amended) The method of claim 113, wherein the proton pump [inhibiting agent] inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

124. (Amended) The method of claim 113, wherein the amount of the proton pump [inhibiting agent] inhibitor is about [5] 2 mg to about 300 mg.

125. (Amended) The method of claim 113, wherein the amount of the proton pump [inhibiting agent] inhibitor is about 10 mg to about [100] 120 mg.

126. (Amended) The method of claim 113, wherein the amount of the proton pump [inhibiting agent] inhibitor is about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

132. (Amended) The method of claim 113, wherein the amount of the buffering agent is about [20] 15 mEq to about [40] 55 mEq.

135. (Amended) The method of claim 113, wherein the buffering agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffereing agent, sodium bicarbonate, potassium bicarbonate, [comprises at least one of] magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, [or] magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum

glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, sodium dihydrogen phosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

139. (Amended) The method of claim 137, wherein the sodium bicarbonate is in an amount from about 1000 mg to about [1680] 2000 mg

140. (Amended) The method of claim 137, wherein the sodium bicarbonate is in an amount of at least about [800] 400 mg.

143. (Amended) The method of claim 141, wherein the calcium carbonate is in an amount from about [500] 1000 mg to about [1000] 2000 mg.

144. (Amended) The method of claim 141, wherein the calcium carbonate is in an amount of at least about [800] 400 mg.

146. (Amended) The method of claim 113, wherein the composition further comprises at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a [excipient,] colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent,

or an isotonic agent, and combinations or any of the foregoing [or a pharmaceutically compatible carrier].

147. (Amended) The method of claim 113, wherein the subject has a[n] gastric acid related [gastrointestinal] disorder.

148. (Amended) The method of claim 147, wherein the disorder is selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, heartburn, esophageal disorder, and acid dyspepsia.

149. (Amended) The method of claim 113, wherein the composition further [comprising] comprises one or more [a] flavoring agent comprising aspartame, thaumatin, sucrose, dextrose, or a chocolate, a cocoa, a cola, a peppermint, a spearmint, a watermelon, an apple, a caramel, a meat, a root beer, [peppermint, spearmint, or watermelon,] a maple, a cherry, a coffee, a mint, a licorice, a nut, a butter, a butterscotch, a butter pecan, or a peanut butter flavoring, and combinations of any of the foregoing.